UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION V

DATE: October 6, 1993

SUBJECT: ATSDR Multi-state Lead Study Protocol Planning Meeting

FROM: Pat Van Leeuwen, Toxicologist
Technical Support Unit

I attended a meeting at the ATSDR headquarters in Atlanta, Georgia, on September 16 and 17, 1993. The purpose of the meeting was to try to reach some agreement between EPA, ATSDR and the state agencies involved in the Tri-State (Illinois, Missouri and Kansas) and Palmerton (Pennsylvania) blood lead studies regarding access to the data for use in field testing of the EPA Lead IEUBK Model. The meeting was attended by three EPA representatives from Headquarters and one representative each from Regions III, V and VII, State representatives from the Missouri Dept of Health and IDPH, and ATSDR personnel representing both the Atlanta office and the Regions (see Attendance list). I represented the Region V interests in obtaining a complete set of the environmental data, with geographical locators, and access to the blood lead and questionnaire data; however, it became obvious that Region V's interests could not be met and that access to the data would be allowed only during the Model field testing exercises, when it could be examined in depth.

The meeting began with a welcome and introduction by Dr. Jeff Lybarger, head of the ATSDR research division, followed by opening remarks by Dr Gershon Bergeisen, TIB, EPA. Both men stressed the need for their agencies to work together and their commitment to work out an acceptable protocol which would allow EPA access to the ATSDR blood lead data. During the following presentations, the complexity of the situation became apparent.

ATSDR has repeatedly stated that they have a copy of all the data from all the sites under discusion. The description of the Multi-site Studies dataset presented by Dr. McGeehin, ATSDR, revealed that the ATSDR dataset consists of 2200 records for all individuals whose blood lead/urinary cadmium levels were measured as part of either the Tri-State or Palmerton studies, keyed to 560 variables which describe the exposure (both

environmental data and questionnaire responses) and the additional biological parameters which ATSDR measured. The data from all four study areas have been merged into a single dataset. Only 66% of the records contain environmental data, but EPA did not consider this to be a problem as we do not plan to review adult data, and environmental data was collected for all children in the study. It was also revealed that the dataset is in the SAS format and the EPA field team would have to include someone knowledgeable in SAS, who could convert the data to an ASCII file for use in the EPA Model.

What appears to be missing from the data set are the geographical locators (site locations where environmental/health data was collected), which ATSDR maintains that they do not have themselves (and do not have access to). Further discussion revealed that the geographical sampling location data was retained by the state agencies. IDPH has sole possession of the data for the Granite City study. An EPA contractor collected the environmental data, accompanied by an IDPH staff member who provided sample identification numbers for the sample locations. Tom Long (IDPH) informed us that the only way EPA could have this data was if the contractor illegally collected it! He also stated his reluctance to release it to ATSDR or EPA, citing a fear of suits for devaluation of study participants' property. Jeff Lybarger stated that in concept we could have access to all the data as along as the state agencies agree. This being the case, we wrote into the Field Test Protocol, provisions to examine the dataset to determine the appropriate exposure unit (e.g., participant's yard, block, neighborhood) for use in the Lead Model. IDPH agreed to cooperate in this matter; it remains to be seen as to what level of detail on the geographical data will be provided by the states. The Missouri Dept. of Health had no concerns regarding the release of the data; the Kansas and Pennsylvania agencies were not present.

We also discussed the type of reports which would be prepared by ATSDR and the state agencies, and how the EPA review might conflict with these reports. IDPH was particularly sensitive to this issue and wanted some assurance that EPA would not come in and manipulate the dataset to show that the IDPH report was done incorrectly or reached inappropriate conclusions. Further discussions revealed the scope of each of the reports and why IDPH was concerned over EPA's request to examine the dataset. The ATSDR report will use the cross-sectional study design to focus on correlations of lead uptake (as reflected in the blood lead level) with other measured environmental and health parameters. The report will also examine the relationship between blood lead level and other biological measurements. The IDPH report will focus primarily on the relationship between lead uptake (as reflected in the blood lead level) and environmental exposure, seeking to identify the source and magnitude of effect of the exposure. The latter report will also use geographical data, as opposed to the study vs control population comparison

used in the ATSDR report, in their evaluation. The IDPH report may, therefore, reach conclusions that appear to differ with EPA decisions at this Superfund site. It is likely that Region V will be called on to respond to the findings of either or both reports.

The major portion of the meeting was devoted to the discussion of statistical methods and the description of these methods in the draft protocol EPA had prepared in advance, as the methodology section was particularly vague. A timeline for the review of the protocol and subsequent visit(s) by EPA to Atlanta for the Field Test of the dataset was prepared. The schedule suggested is as follows:

9/17/93	Draft protocol for review by EPA/ATSDR/States
9/24/93	Agencies review/comments provided to EPA (HQ)
9/27/93	EPA revises protocol
10/01/93	Draft protocol to ATSDR for Peer review
10/22/93	ATSDR Peer review completed
10/27/93	EPA addresses Peer Review comments and finalizes protocol
11/93	Arrange for EPA field test 1st-2nd week

The meeting was interupted several times by attacks by both ATSDR and IDPH on EPA's risk assessment methodology and risk assessment tools, including the Lead IEUBK model. It was quite clear that ATSDR believes that modeling is less desireable and predictable than health studies and that such studies, especially blood lead studies, should be done at every Superfund site. EPA maintains that blood lead studies are equally poor predicters of risk because they represent a snapshot in time, are susceptible to selection bias, inaccuracies in the blood lead measurement and behavior changes in the sample population due to education and other outreach programs; furthermore, they do not predict future community risk. All agencies agreed that if a reliable lead model could be developed, it would be a useful and welcome tool, and EPA assured all present that additional and more focused blood lead studies need to be done before the EPA Lead Model can be considered to be final. Version. 1.0 of the IEUBK Model is to be considered as the first approved version, not the final version. In the end, representatives of all agencies seemed to reach a working understanding of the other agencies' perspectives and needs, at least for the duration of the meeting.

The following is what I gained from the meeting:

* The labels for the eight columns of data for Granite City study provided on disk by ATSDR in July 1993. Also the realization that data set probably contains adult data as well as data for children through age six.

* A list of the 560 variables, their position in the data set, and the labels for the ATSDR Multisite Dataset.

* A draft Protocol of the Field Test of the Integrated Exposure/Uptake/Biokinetic Model for Lead Exposure, which was at least agreeable to all members present (including IDPH). This draft was revised within EPA, following the agreed upon timeline, and resubmitted to ATSDR for internal review.

* The assurance from both ATSDR and IDPH that they would cooperate in providing access to all data specified in the protocol in a timely manner.

* The assurance that we would be provided with a copy of the IDPH report on the study done at Granite City before it was released for external review. The changes to IDPH's draft report were provided to ATSDR, the first reviewer, at the meeting. We should expect to receive a copy of the final report soon.

* The assurance that we would be provided with a copy of the ATSDR report on the study done at Granite City before it is released for external review. We were provided with a copy of the ATSDR report "Biological Indicators of Exposure to Cadmium and Lead, Part I" for the Palmerton, Pennsylvania site and told that the Tri-State report would follow the same format.

* The assurance from ATSDR that they would allow a team of EPA personnel, including members from the Regions, unlimited access to the ATSDR dataset during the field test.

* The assurance that all future studies would be structured as to allow equal access of data to ATSDR, EPA and the state agencies and review of each ensuing report by all participating agencies.

* A two page evaluation of the application of the EPA Lead Model (version 0.5) and comparison of the results with the results from a regression model, prepared for IDPH by Maurice Lavois, the statistian subcontracted by IDPH for the ATSDR blood lead study at the Granite City site. Tom Long,IDPH, requested comments on the presentation (enclosed).

What I hoped for, but did not get:

* Any geographical location data which tells where the environmental data on the computer dataset we received from ATSDR was taken. The Illinois study included samples from the entire Granite City area, and from the adjacent towns of Madison and Venice. Exposures vary with location. Thus our computer dataset is relatively useless.

* Any correlating questionnaire data on the above data set, such as age and sex of study participants, where they spend their time, etc., which would allow meaningful evaluation of the dataset.

* Correlated blood lead data, even without geographical location indicators.

Please feel free to call me at 6-4904 if you wish to discuss the meeting in more detail or see any of the above items.

cc Dave Ullrich
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ATSDR / EPA / STATES

MULTI-STATE LEAD STUDY PROTOCOL PLANNING MTG.

SIGN - IN

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EPA BLOOD LEAD PREDICTION MODEL
(LEAD-5)

MODEL WEIGHTS ASSIGNED TO MAJOR SOURCES
OF RESIDENTIAL LEAD EXPOSURE
(Children ages 0.5 to 7 years)

MEAN PREDICTED BLOOD LEAD (for age range)	3.11 ug/dL
MEAN ESTIMATED TOTAL UPTAKE	10.38 ug/day

UPTAKE FROM SIX ENVIRONMENTAL SOURCES:

MEAN SOIL+DUST UPTAKE	6.00 ug/day
MEAN DIETARY UPTAKE	3.27 ug/day
MEAN DRINKING WATER UPTAKE	0.99 ug/day
MEAN PAINT UPTAKE	0.00 ug/day
MEAN AIR UPTAKE	0.12 ug/day

SOURCE SPECIFIC WEIGHTING FACTORS (TOTAL UPTAKE / SOURCE OF UPTAKE)	MODEL WEIGHT	GCLS[1] WEIGHT
BUILDING CONDITION AND RECENT REFINISHING WORK[2]		48%
SOIL+DUST UPTAKE[3] (INCLUDES LEAD FROM PAINT DUST)	58%	(48%)
SOIL+DUST[3] (EXCLUDING PAINT)		13%
SOIL[3] (EXCLUDING DUST)		(4%)
DIETARY UPTAKE	32%	NA
DRINKING WATER UPTAKE	10%	1%
PAINT UPTAKE[3] (GCLS WEIGHT INCLUDES LEAD FROM PAINT DUST)	0.00	38%
AIR UPTAKE	1%	NA

NOTE: 1. GCLS weights are based upon percent of total blood lead variance accounted for by each source in regression analysis against blood lead.

2. These factors primarily reflect the contribution of paint, but their variance is removed from the contribution of paint in the weights presented above.

3. The contribution of paint lead and soil lead to dust lead is based on regression analysis against dust lead.

EPA LEAD-5 MODEL:

OBSERVED AND PREDICTED BLOOD LEAD LEVELS
USING GRANITE CITY LEAD DATA[1]

STRATA	BLOOD LEAD OBS.; PRED.	OVER[2] (UNDER)	ENVIRONMENTAL LEAD[3]: SOIL	DUST	WATER
TOTAL	6.9 9.3	35%	450	1283	3.3
BPB GROUP:					
$HIGH_{BPB}$	15.8 20.0	27%	642	3263	3.1
LOW_{BPB}	5.3 8.0	51%	421	1014	3.6
EPA GROUPS:					
$HIGH_{SOIL}$	8.3 18.5	123%	914	2761	4.8
LOW_{SOIL}	6.4 6.0	(6%)	258	779	2.9
$HIGH_{SOIL}$	9.6 18.0	88%	844	2761	2.4
LOW_{SOIL}	6.1 8.4	38%	368	1142	3.5

NOTES:
1. Model defaults used for AIR; FOOD; PAINT; MATERNAL
2. OVER/UNDER is percent PREDICTED varies from OBSERVED.
3. Arithmetic means used for all values.

This table demonstrates that:

A. The EPA Lead 5 Model over estimates blood lead levels in general;

B. The EPA model is very sensitive to the input value for SOIL+DUST;

C. For high SOIL+DUST input values the model greatly overestimates blood lead levels.

D. The EPA model assumes that 100% of lead uptake can be accounted for by environmental measures.

The GCLS data show that only about 1/4 of blood lead variance can be accounted for using environmental lead measures. Even if food accounts for 32% of the total lead uptake, as in the EPA model, most blood lead variance is not accounted for by environmental measures. Individual factors - mainly social, behavioral, and economic - account for most of the blood lead variance, and should be regarded as primary targets for intervention.